

## **REMARKS**

### **1. Status of Application**

The present application, Ser. No. 10/603,129, includes claims 23-45 and was filed on June 24, 2003. Applicant thanks the Examiner for withdrawing the rejections set forth in the June 24, 2005 Office Action. The claims have been amended as reflected in the listing of claims above. Applicant respectfully submits that the examiner's rejections contained in the November 3, 2005 Office Action have been traversed, and therefore, that the present application is in condition for allowance.

Claim 23 has been amended to restate the claim as a Product by Process claim, which places a method limitation which does structurally further limit the product. In addition, claims 39-41 have been amended to clarify that the silicone used must be of the type that is formulated to allow the specific method of curing stated, which does structurally further limit the product claim.

### **2. Claim Rejections under 35 U.S.C. § 102**

#### **a. Yan**

The Examiner provided a new rejection of claims 23-25, 28-31, 35-36, and 45 based upon 35 U.S.C. § 102(b), under U.S. Patent No. 4,960,425 to Yan et al. ("Yan"). The Examiner stated that "Yan discloses a medical article, breast implant (abstract), comprising a shell defining an interior cavity, said shell being formed of at least one layer of a non-olefin polymer material, wherein said shell is textured (column 8, lines 5-33), seamless (column 7, lines 5-15), filled with a silicone gel, a saline solution, or a foam (column 2, lines 32-47), wherein the

polymer material is silicone, polyurethane, or elastomer (column 8, line 5-33).” Applicant respectfully submits that claim 23 and dependent claims 39-41, as presently amended, overcome the Examiner’s rejection under 35 U.S.C. § 102(b) based on Yan. Furthermore, claims 24-25, 28-31, 35-36, 42, and 45 overcome the Examiner’s rejection under 35 U.S.C. § 102(b) based on Yan due to their dependence on allowable claim 23.

Applicant respectfully submits that claim 23, as presently amended to recite a “medical article obtained by the process of rotational molding,” is not anticipated by Yan. Yan teaches only a medical article, without the product by process limitation of rotational molding. (*See* M.P.E.P. § 2173.05(p)). Therefore, Yan does not teach an express limitation of claim 23 as presently amended, and it does not anticipate under 35 U.S.C. § 102(b).

Applicant further submits that claims 39-41, as presently amended to recite “the medical article of claim 23 where the polymer material is a silicone formulated so that it may be [cured in a certain manner].” Yan does not disclose specific types of silicone. Therefore, Yan does not teach the express limitations of claim 39-41 as presently amended, and it does not anticipate under 35 U.S.C. § 102(b).

Since Yan fails to anticipate limitations expressly recited by claim 23, Yan cannot anticipate the inventions recited by those claims that depend from claim 23. Therefore, claims 24-25, 28-31, 35-36, and 42, all of which depend from Claim 23, are not anticipated by Yan. Applicant respectfully requests that the Examiner withdraw the rejection of claims 23-25, 28-31, 35-36, and 39-42.

**3. Claim Rejections under 35 U.S.C. § 103(a)****a. Yan**

The Examiner rejected claims 32-34 and 37-38 under 35 U.S.C. § 103(a) as unpatentable over Yan. Applicant previously withdrew claims 37-38 in Response G, mailed August 9, 2005, to June 24, 2005 Office Action. Applicant respectfully submits that claims 32-34 are patentable over a fair reading of Yan.

The Examiner admits that Yan “does not specifically disclose a removable liner.” Although, the Examiner goes on to note that it would have been obvious to provide a removable liner for the protection of the device, Applicant respectfully urges the Examiner that neither Yan, nor any other cited prior art discloses or suggests a removable liner. Furthermore, there is no support for the use of a removable liner for the protection of the device either in the disclosure of the present application, which specifies the use of a removable liner to make the molded product seamless, or in the prior art. Therefore, Applicant submits that the Examiner has failed to cite a combination of prior art which discloses each and every claim limitation, which thus renders the present rejection an impermissible “obvious to try” rejection (M.P.E.P. §§ 2143.03, 2144, 2145 X.B). Nor does the Examiner cite to any teaching or suggestion in Yan, or anywhere else in the prior art, to provide a removable liner for a medical article such as the one in claim 23. (*Id.*, §§ 2143.01, 2143). As such, Applicant submits that the present rejection of claims 32-34 would also fail to meet the Examiner’s burden of producing a case of *prima facie* obviousness (*Id.*, §§ 2142, 2143). Applicant respectfully requests that the Examiner withdraw the rejection of claims 32-34.

**b. Yan in view of XP-002334285**

The Examiner rejected claims 27 and 43-44 under 35 U.S.C. § 103(a) as unpatentable over Yan in view of XP-002334285. Applicant respectfully submits that claims 27 and 43-44 are patentable over a fair reading of Yan and XP-002334285.

Applicant incorporates by reference here the arguments presented above traversing the Examiner's rejection of claim 32-34 under 35 U.S.C. § 102(e) as anticipated by Yan. As noted by the Examiner, Yan fails to disclose the specific range recited in claim 27. XP-002334285 does disclose that "with the advent of the computer, it is now possible to control the thickness of the object to a good degree of accuracy." However, nothing in either Yan or XP-002334285, or anywhere else in the prior art, suggests altering the range disclosed in Yan, or specifies the advantages of the range selected in claim 27. As such, Applicant submits that the present rejection of claim 27 would also fail to meet the Examiner's burden of producing a case of *prima facie* obviousness (M.P.E.P. §§ 2142, 2143). Applicant respectfully requests that the Examiner withdraw the rejection of claim 27.

Furthermore, as noted by the Examiner, Yan fails to disclose that the shell of the prosthesis is formed from a solvent based polymer or a polymer which emits gaseous by-products during curing. XP-002334285 states that "in the production of cosmetic hand prostheses, silicone rubber dissolved in a solvent is commonly used," and discusses the diffusion of gasses in room-temperature cured silicone. However, nowhere in XP-002334285, Yan, or the other prior art, is there any teaching or suggestion to make a medical article, such as that of claim 23, where the polymer material is solvent-based, as in claim 43, or where the polymer material emits gaseous by-products during curing, as in claim 44. Applicant respectfully requests that the Examiner withdraw the rejection of claims 43-44.

**c. Yan in view of Prah**

The Examiner rejected claim 26 under 35 U.S.C. § 103(a) as unpatentable over Yan in view of Prah (US 4,426,742). Applicant respectfully submits that claim 26 is patentable over a fair reading of Yan and Prah.


Applicant incorporates by reference here the arguments presented above traversing the Examiner's rejection of claim 32-34 under 35 U.S.C. § 102(e) as anticipated by Yan. As noted by the Examiner, Yan fails to disclose a device wherein the shell of the prosthesis is patchless. Prah does disclose "an adapter type molding that consists of the same material of which the cup of the prosthesis is made." Prah also discloses that the adapter type molding may be made of a different material. Nothing in Yan, Prah, or other prior art, teaches or suggests a patchless shell for a medical device obtained by a rotational molding process, such as that of claim 23, nor is there any suggestion to combine or an indication that there is a problem with a non-patchless shell in such a device. Applicant submits that the present rejection of claim 26, thus, fails to meet the Examiner's burden of producing a case of *prima facie* obviousness (M.P.E.P. §§ 2142, 2143). Applicant respectfully requests that the Examiner withdraw the rejection of claims 26.

**CONCLUSION**

It is respectfully submitted that the present application is in condition for allowance and prompt notification thereof is requested. If the prosecution of this application can be advanced by a telephone conference, the Examiner is requested to call the undersigned at (212) 530-5363.

Respectfully submitted,

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